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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,570	01/23/2004	Pamela M. Drake	340082.401	4880

500 7590 04/22/2009

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EXAMINER	
BARNHART, LORA ELIZABETH	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
04/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,570	DRAKE ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office action is identical to the final rejection mailed 6/16/08.

Response to Amendments

Applicant's amendments filed 3/21/08 to claim 1 have been entered. Claim 2 has been cancelled. No claims have been added. Claims 1, 5, 7, and 8 remain pending in the current application, of which claims 1, 5, and 7 ONLY are being considered on their merits. Claim 8 remains withdrawn from consideration at this time. Prior art references not included with this Office action can be found in a prior action.

Claim Rejections - 35 USC § 112

The rejections of record under 35 U.S.C. § 112 are withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 103

Any rejections of record under 35 U.S.C. § 103 not specifically addressed below are withdrawn in light of the claim amendments. These claim amendments, however, necessitated a new search that yielded new grounds of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (2002, U.S. Patent 6,461,607; reference AE on 9/23/04 IDS) taken in view of Ridgway et al. (1988, U.S. Patent 4,725,440; reference A), Chen (1998, U.S. Patent 5,837,254; reference B), and Paul (1996, U.S. Patent 5,531,989; reference C).

Farmer teaches a composition for oral administration comprising one or more species or strains of probiotic lactic acid-producing bacteria and fructooligosaccharides (column 5, lines 33-46; column 6, lines 33-48; column 17, lines 19-67; column 22, line 23, through column 26, line 35; and Formulation 1 in Figure 4). The composition of Farmer is useful for combating gastrointestinal effects of antibiotic therapy on animals (column 3, line 62, through column 4, line 7; and column 5, lines 13-30, e.g.) Farmer teaches that the composition may comprise vitamins including vitamin C (column 23, line 66, through column 24, line 23; and column 25, lines 22-67). Farmer teaches that the composition may be coadministered with an anti-fungal agent such as nystatin (column 7, lines 1-5). Farmer teaches that any combination of probiotic bacteria may be included in the composition so long as the bacteria produce lactic acid and demonstrate beneficial function within the gastrointestinal tract (column 12, line 44, through column 13, line 58). Farmer teaches that the composition may be formulated and packaged as the skilled artisan deems necessary (column 35, lines 41-57, e.g.).

Farmer does not teach a kit in which the anti-fungal agent is provided separately from the other components of the composition. Farmer does not teach all of the bacterial species recited in claim 7.

Ridgway teaches pastilles comprising nystatin for treating oral and esophageal candidiasis (Abstract; column 2, lines 43-66; and column 6, line 53, through column 9, line 31). The pastille of Ridgway may be dissolved in the mouth of the animal being treated, thereby yielding a slow release of nystatin to the oral cavity and esophagus, which Ridgway teaches improves the treatment of candidiasis (column 1, lines 38-52; and column 3, lines 45-55).

Chen teaches that oral and esophageal candidiasis are side effects of the administration of antibiotics (column 3, lines 4-17).

Paul teaches a composition comprising any of numerous probiotic bacteria, including those recited in claim 7, and fructooligosaccharides (column 3, line 59, through column 4, line 30).

A person of ordinary skill in the art would have had a reasonable expectation of success in providing bacteria, fructooligosaccharides, and vitamin C in one formulation as directed by Farmer and providing nystatin in a second formulation as directed by Ridgway because the cited prior art teaches that the active agents may be combined as necessary to treat gastrointestinal conditions brought on by the administration of antibiotics. The skilled artisan would have been motivated to provide nystatin in a formulation separate from the bacteria/FOS/vitamin C formulation because Ridgway

teaches that controlled dosing of nystatin improves the treatment of oral and esophageal candidiasis.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include any and all of the bacterial species taught by Paul in the composition of Farmer because Paul teaches that these bacteria are beneficial to the gastrointestinal tract and produce lactic acid (column 4, lines 22-30), which are the criteria set forth by Farmer for inclusion of bacteria in the composition (column 12, lines 44-48). Furthermore, Paul explicitly teaches providing said bacteria with fructooligosaccharide.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a kit comprising a first component that comprises probiotic bacteria (including those recited in claim 7), fructooligosaccharide, and vitamin C and a second component comprising a slow-release dose of nystatin to treat gastrointestinal infections caused by antibiotic administration because Farmer, Paul, and Chen teach that all of these components are useful for such treatment, and because Ridgway teaches an advantage to supplying nystatin separately.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's comments regarding the rejections of record have been considered to the extent they read on this new ground of rejection. Regarding the withdrawn rejection over Farmer (U.S. Patent 6,645,606) taken in view of Jaffe, applicant alleges that the art does not teach a composition for oral administration (Reply, pages 7-9). Regarding the

rejection of record over Wynne taken in view of Muramatsu and Costanzo, applicant supplies with the instant reply a declaration under 37 C.F.R. 1.131 (hereafter "the Drake declaration II") as evidence of possession of the instant invention prior to 9/1/01 (Reply, page 10). These arguments have been fully considered, but they are not persuasive.

As discussed above, the cited prior art explicitly teaches orally administrable compositions for the treatment of gastrointestinal conditions caused by antibiotic therapy. The cited prior art also suggests providing nystatin in a dose form separate from the rest of the active agents.

Regarding the Drake declaration II, the date for which Farmer ('607) is available as prior art is 8/24/98, the date of the provisional U.S. application. Therefore, the Drake declaration II does not remove Farmer ('607) as prior art.

Claims 1, 5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wynne et al. (2003, WO 03/033681) taken in view of Muramatsu et al. (1994, U.S. Patent 5,334,516), Costanzo et al. (1996, U.S. Patent 5,518,740), Ridgway et al. (1988, U.S. Patent 4,725,440), and Chen (1998, U.S. Patent 5,837,254).

Wynne teaches a composition comprising the probiotic bacterium *Lactobacillus pentosus* NCIMB 41114 in combination with an antibiotic (*e.g.*, tetracycline) or antifungal agent (*e.g.*, fluconazole) (page 6, lines 22-29). The composition of Wynne may be a single dosage form comprising all of the active ingredients or may be a kit with separate components (page 6, lines 29-31). The composition of Wynne may take any of numerous forms and is suitable for oral administration (page 6, lines 9-12 and 19-22).

Wynne teaches that coadministering *L. pentosus* NCIMB 41114 with an antibiotic mitigates the side effects or the antibiotics (page 6, line 24).

Wynne does not teach a composition comprising a bacterium and an antimicrobial agent as well as fructooligosaccharides and ascorbic acid. Wynne does not teach a kit in which the components are separated as in the instantly claimed invention.

Muramatsu teaches that fructooligosaccharide is a branched sugar that promotes the proliferation of probiotic bacteria, including *Lactobacillus,* in the intestines of a subject when ingested by said subject (column 1, lines 11-20).

Costanzo teaches a yogurt composition for oral ingestion that comprises probiotic bacteria as well as ascorbic acid (Examples 1-5 at column 10, line 15, through column 14, line 48).

Ridgway teaches pastilles comprising nystatin for treating oral and esophageal candidiasis (Abstract; column 2, lines 43-66; and column 6, line 53, through column 9, line 31). The pastille of Ridgway may be dissolved in the mouth of the animal being treated, thereby yielding a slow release of nystatin to the oral cavity and esophagus, which Ridgway teaches improves the treatment of candidiasis (column 1, lines 38-52; and column 3, lines 45-55).

Chen teaches that oral and esophageal candidiasis are side effects of the administration of antibiotics (column 3, lines 4-17).

A person of ordinary skill in the art would have had a reasonable expectation of success in including the fructooligosaccharide of Muramatsu and the ascorbic acid of

Costanzo in the composition of Wynne because Muramatsu and Costanzo teach that fructooligosaccharide and ascorbic acid may be orally administered. The skilled artisan would have been motivated to include fructooligosaccharide and ascorbic acid in the composition of Wynne because Muramatsu and Costanzo teach that they each increase the number of probiotic bacteria in the intestines, and because Wynne teaches that the bacteria/antimicrobial composition is intended to promote intestinal flora.

The probiotic bacteria of Wynne and Costanzo, the fructooligosaccharide of Muramatsu, and the ascorbic acid of Costanzo all improve the state of intestinal flora. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See M.P.E.P. § 2144.06 and *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

A person of ordinary skill in the art would have had a reasonable expectation of success in providing bacteria, fructooligosaccharides, and vitamin C in one formulation as directed by Wynne, Costanzo, and Muramatsu and providing nystatin in a second formulation as directed by Ridgway because the cited prior art teaches that the active agents may be combined as necessary to treat gastrointestinal conditions brought on by the administration of antibiotics. The skilled artisan would have been motivated to provide nystatin in a formulation separate from the bacteria/FOS/vitamin C formulation

because Ridgway teaches that controlled dosing of nystatin improves the treatment of oral and esophageal candidiasis.

The selection of the form of the composition of Wynne taken in view of Muramatsu and Costanzo would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Wynne teaches that the composition may be administered in any of numerous forms through any of numerous avenues. A holding of obviousness over the cited claims is therefore clearly required.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to include fructooligosaccharide and ascorbic acid in the orally ingestible composition of Wynne because Muramatsu and Costanzo teach that oral administration of these components promotes probiotic bacterial growth in the intestines. It would have been further obvious to provide a kit comprising a first component that comprises probiotic bacteria (including those recited in claim 7), fructooligosaccharide, and vitamin C and a second component comprising a slow-release dose of nystatin to treat gastrointestinal infections caused by antibiotic administration because Wynne, Muramatsu, and Costanzo teach that all of these components are useful for such treatment, and because Ridgway teaches an advantage to supplying nystatin separately.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's comments regarding the rejections of record have been considered to the extent they read on this new ground of rejection. Regarding the rejection of record

over Wynne taken in view of Muramatsu and Costanzo, applicant supplies with the instant reply the Drake declaration II, a declaration under 37 C.F.R. 1.131, as evidence of possession of the instant invention prior to 9/1/01 (Reply, page 10). These arguments have been fully considered, but they are not persuasive.

The Drake declaration II is not commensurate in scope with the claimed invention. The Drake declaration II clearly indicates that the bacteria in the composition discussed therein are all isolated from humans (see page 1, item 2, of the product description within the Drake declaration II). Furthermore, the Drake declaration II indicates that the composition therein necessarily comprises *Lactobacillus acidophilus* DDS-1 (see page 1, paragraph 3, of the product description). The instant claims are broader in scope, since claims 1 and 5 are not required to include any particular bacteria from any particular source; all that is required is that the bacteria are "beneficial" in some way. Claim 7 places no limit on the strain of *L. acidophilus* to be included in the formulation. It is not clear that the composition discussed in the Drake declaration II is the same in scope as that instantly claimed. This rejection would be overcome if the claims were amended to be commensurate in scope with the showing of the Drake declaration II.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651